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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Cameron Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
One Maritime Plaza
San Francisco, CA 94111

EXAMINER	
ANDERSON, JAMES D	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/631,116	DEHNAD, HOUDIN	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *1-26 and 43-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 1/11/2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant's arguments with respect to claims 27-42 have been considered but are moot in view of the new ground(s) of rejection.

In light of the new rejections being applied against the claims, this Office Action is Non-Final.

Status of the Claims

Claims 1-48 are currently pending and are the subject of this Office Action. Claims 1-26 and 43-48 are withdrawn from consideration. Claims 27-42 are presently under examination.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 33-35 recite the limitation "substantially" at various lines in the claims. This limitation is indefinite because it is not clear to what extent the polymer is free of

active agent (claims 33 and 35) or to what extent a barrier prevents diffusion of active agent (claim 34). Does "substantially" mean less than 1%? 10%? 20%? Applicant's arguments have been considered but are not persuasive. Applicant directed Examiner to MPEP 2173.05(c)(D). Examiner is aware of this section of the MPEP. Applicant asserts that the Courts "repeated [*sic*] held that the term 'substantially' recited in a claim is definite". This is, however, not the case. For example, the term "substantial portion" was held to be indefinite because the specification lacked some standard for measuring the degree intended (*Ex parte Oetiker*, 23 USPQ2d 1641 (Bd. Pat. App. & Inter. 1992). In the instant case, claims 33 and 35 recite the limitation "substantially free" from an active agent. As was the case in *Ex parte Oetiker*, the instant specification lacks a standard for measuring the degree intended.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27-33 and 35-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ding *et al.* (U.S. Patent No. 5,837,313; prior art of record) in view of Flanagan (U.S. Patent No. 6,764,709; Issued Jul. 20, 2004; Filed Nov. 8, 2001) (newly cited).

The instant claims are drawn to a method of manufacturing a drug eluting implantable medical device, comprising applying a composition comprising a polymer, an active agent and a solvent, allowing the solvent to evaporate and subsequently directing a beam of charged particles to the dry polymeric coating.

Ding *et al.* disclose a method of coating an implantable open lattice metallic stent comprising sequentially applying a plurality of relatively thin outer layers of a coating composition comprising a solvent mixture of uncured polymeric silicone material and crosslinker and finely divided biologically active species. Agents suitable for incorporation include antithrobotics, anticoagulants, antiplatelet agents, thrombolytics, antiproliferatives, antinflammatories and agents that inhibit hyperplasia and in particular restenosis (col. 4, lines 63-66). This teaching reasonably suggests and motivates the instantly claimed derivatives of rapamycin (which are known antiproliferatives and prevent restenosis). The coatings are cured and subjected to argon gas plasma and exposure to gamma radiation, electron beam, ethylene oxide or steam sterilization (Abstract; col. 4, lines 21-25). In the plasma treatment, coated stents are placed in a reactor chamber and inert gas (*e.g.*, argon) is admitted to the reactor chamber at varying power ranges and flow rates (*id.* at lines 26-39). This teaching reasonably correlates with a "directed" beam as such a limitation does not suggest that said beam must be narrow. As such, introducing argon plasma through a flow port meets the claimed limitation of "directing a beam of charged particles". Polymers suitable for the coatings taught in the reference include polyurethanes as instantly claimed (col. 4, lines 48-62). The solvent is evaporated in the curing process, often at elevated temperatures (col. 8, lines 21-37). It flows from the disclosure of Ding *et al.* that such evaporation will result in the residual solvent percentages instantly claimed. With respect to instant claims 33 and 35-36, which recite forming a barrier layer of polymer comprising no active agent, the reference teaches that multiple layers may be employed wherein one or may layers do not contain active agent (col. 10, lines 50-59).

In the absence of a showing demonstrating the criticality of the instantly claimed current density, no unobviousness is seen in adjusting the flow rate and power of the argon plasma treatment in order to reach the claimed current density.

Claims 34 and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ding *et al.* (U.S. Patent No. 5,837,313; prior art of record) as applied to claims 27-33 and 35-37 above, and further in view of WO 03/022323 (Published March 20, 2003) (prior art of record).

Ding *et al.* discloses as discussed *supra*. The reference does not disclose use of a polymer with a percent crystallinity of about 50% as recited in instant claim 34 or exposing the dry coating to a temperature equal to or greater than the glass transition temperature of the polymer in the coating as recited in instant claim 42.

However, WO 03/022323 discloses coatings for reducing the rate of release of drugs from stents and is thus drawn to the same subject matter disclosed in Ding *et al.* WO '323 discloses the use of polymers with crystallinity of not less than 10%, preferably not less than 50% (page 6, ¶ [0017]). This reasonably suggests the limitations of instant claim 34. Further, WO '323 discloses that when thermoplastic polymers are used (such as the instantly claimed polymers), the deposited primers should be exposed to heat at a temperature greater than the glass transition temperature of the selected polymer (page 15, ¶ [0017]) thus teaching the limitation of instant claim 42.

In the absence of a showing of unexpected results commensurate in scope with the claims, the instantly claimed methods would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. WO '323 explicitly motivates the skilled

artisan to use polymers with crystallinity of not less than 10%, preferably not less than 50% and exposing polymers to heat at a temperature greater than the glass transition temperature of the selected polymer. The motivation to combine the references is reasonably suggested wherein all of the references are drawn to medical devices identically coated with polymers and active agents.

Claim 38 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ding *et al.* (U.S. Patent No. 5,837,313; prior art of record) as applied to claims 27-33 and 35-37 above, and further in view of EP 0970711.

Ding *et al.* discloses as discussed *supra*. The reference does not disclose masking a portion of the coating by inserting a mandrel prior to directing a beam of charged particles as required by the limitations of claim 38.

However, EP '711 discloses a method of controlling the thickness of a polymer coating applied to the inner surface of a stent by fitting a mandrel within its interior (¶ [0006]). This mandrel is disclosed to minimize or eliminate polymer coating on the inner surface of the stent. EP '711 also discloses the same polymeric coating instantly claimed (¶ [0023] to [0025]) as well as a polymeric coating comprising the therapeutic agent rapamycin (¶ [0030] and Example 7).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the mandrels disclosed in EP '711 to protect the inner surface of an implantable medical device (*e.g.* a stent) from the argon plasma disclosed in Ding *et al.* One skilled in the art would be motivated to do so because EP '711 discloses that it is often desirable for the inner and outer surfaces of implantable stents to have different properties, including drug

elution profiles. Further, the skilled artisan would have been imbued with at least a reasonable expectation that exposure of the outer polymer to a beam of charged particles while protecting the inner polymer, would result in different chemical and structural properties of the respective polymers. The motivation to combine the references is reasonably suggested wherein all of the references are drawn to medical devices identically coated with polymers and active agents.

Claims 39-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ding *et al.* (U.S. Patent No. 5,837,313; prior art of record) as applied to claims 27-33 and 35-37 above, and further in view of Yang *et al.* (U.S. Patent No. 6,120,847).

Ding *et al.* discloses as discussed *supra*. The reference does not disclose exposing the dry coating to a fluid to remove polymer fragments from the coating as required by the limitations of claims 39-41.

However, Yang *et al.* disclose a surface treating method for stent coating that eliminates surface imperfections on a medical device having a drug release coating including a therapeutic substance in a polymeric carrier disposed on at least a portion of the medical device (Abstract). The polymers used in the coatings include the instantly claimed poly(L-lactide) (col. 3, lines 31-44). The applied coating comprises a solvent, a polymer, and a therapeutic agent and the solvent is evaporated to leave on the stent surface a coating of the polymer and the therapeutic agent (col. 4, lines 1-2 and 24-27). Because the procedures for applying the polymeric surface treatments leave polymeric fibers, polymeric particles or other polymeric surface aberrations, there is a need to eliminate or reduce the unwanted imperfections. As such, Yang *et al.* disclose a method of contacting a coated stent having polymeric imperfections with a vaporized solvent

(col. 5, lines 18-35). Organic solvents can be used and the reference states that not only the vapor, but also the fluid itself can be used to remove polymer imperfections (col. 5, lines 36-44 and 57-60). This teaching reasonably suggests that any solvent with the same properties (*e.g.* capability to remove surface imperfections) could also be used.

In the absence of a showing of unexpected results commensurate in scope with the claims, the instantly claimed methods would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Yang *et al.* provide the motivation to contact a coated stent with a solvent wherein it is disclosed that such contact can remove polymeric imperfections from the coated stent. The motivation to combine the references is reasonably suggested wherein all of the references are drawn to medical devices identically coated with polymers and active agents.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

April 13, 2007

PHYLLIS SPIVACK
PRIMARY EXAMINER
4/13/07